

Policy Title :

**Reduction and detection of bacterial contamination
of blood components**

Department	Index No.	Scope
Laboratory & Blood Bank	LAB-124	All Blood Bank Staff
Issue Date	Revision NO	Effective Date
1438/3/9	2	1440/08/23
Review Due Date	Related Standard NO.	Page Number#
1442/08/23	CBAHI (LB.51)	8

01. Policy:

- 01.1. The Blood Bank has a process to limit and to detect bacterial contamination of blood components.

02. Definition :

- 02.1. N/A

03. Purpose :

- 03.1. To reduce the risk of bacterial contamination of blood components to prevent bacterial transmission to the patient.
- 03.2. To prevent bacterial contamination related blood transfusion reactions.

04. Procedure :

The Blood Bank technician follows 5 steps:

1. Arm cleansing

- 1.1. The Blood Bank technician scrubs 4 cm area in all directions from intended site with 2% iodine solution or with alcohol swab for 30 seconds. Then applies 10% iodine swab stick, starting at the center with concentric spiral outward for 30 seconds.
- 1.2. Before venipuncture, the Blood Bank technician checks the blood bag and the tubing for evidence of leaks, discoloration, particulate contamination.
- 1.3. The Blood Bank technician clamps the tubing near the needle before the needle cover is removed.

2. Diversion of donation

- 2.1. The Blood Bank technician diverts a minimum of 20 mL of the first part of every blood donation into a



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side-arm pouch.

3. Optimizing blood component processing and storage:

- 3.1. The Blood Bank technician checks and optimizes the storage temperature and the expiry date of blood components.
- 3.2. The Blood Bank technician limits storage time for platelets units for 5 days only and with the exact time of expiry.
- 3.3. The Blood Bank technician performs universal leukoreduction for the blood components.

4. Pretransfusion bacterial detection:

- 4.1. Visual inspection of blood components
- 4.2. The Blood Bank technician inspects the blood products for the following:
 - 4.2.1. Turbidity.
 - 4.2.2. Discoloration.
 - 4.2.3. Intact and dry packaging
 - 4.2.4. Attached blood label and/or lot number
 - 4.2.5. Intact ports and/or caps.
- 4.3. If any abnormality or discrepancy of the above observation is found, the blood component and/ or blood product is not issued nor transfused and will be quarantined till investigations.
- 4.4. **Red blood cells**

In addition to the previous criteria, the Blood Bank technician inspects the Red blood cells for the following criteria:

- Discoloration;
- Bacterial contamination;
- Hemolysis
- Particulate matter;
- Lipemia
- Red cells in attached segments have the same appearance as red cells in the bag.

4.5. Platelets

In addition to the previous criteria, the Blood Bank technician inspects the Platelets for the following criteria:

- Discoloration;
- Bacterial contamination;
- Particulate matter;
- Lipemia;
- Red cell contamination;
- Icterus.

In addition to the previous criteria, the Blood Bank technician inspects the Plasma for the following criteria:

- Discoloration
- Bacterial contamination;
- Particulate matter;
- Lipemia;
- Red cell contamination;
- Icterus.

4.7. Cryoprecipitate

In addition to the previous criteria, the Blood Bank technician inspects the Cryoprecipitate for the following:

- Bacterial contamination;
- Lipemia;
- Red cell contamination;
- Icterus

The Blood Bank technician follows the acceptability criteria of blood components and checks the visual guide for

	Red Cells	Platelets	Plasma	Cryoprecipitate
Hemolysis	Some degree of hemolysis is acceptable and expected.	n/a	Some degree of hemolysis is possible depending on number of red cells in plasma.	Some degree of hemolysis is possible depending on the number of red cells in the plasma.
Red cell contamination	n/a	No standards of acceptability for red cell contamination for platelet units.	No standards of acceptability for red cell contamination of plasma units.	No standards of acceptability for red cell contamination of plasma units.
Lipemia	Blood components with lipemia are acceptable for transfusion.			
Icterus	Blood components with icterus are acceptable for transfusion.			
Bacterial contamination	Bacterially contaminated blood components are not acceptable for transfusion.			
Particulate matter	Units containing clots and/or fibrin strands, cellular aggregates, and/or cold agglutinins shall not be transfused. Units containing White Particulate Matter are acceptable for transfusion.	Units containing clots and/or fibrin strands and/or cellular aggregates shall not be transfused.	Units containing clots and/or fibrin strands, and/or cellular aggregates, shall not be transfused. Units containing White Particulate Matter are acceptable for transfusion.	Units containing clots and/or fibrin strands, and/or cellular aggregates, shall not be transfused. Units containing White Particulate Matter are acceptable for transfusion.
Discoloration	Discoloration due to hemolysis and lipemia are acceptable for transfusion. Discoloration due to bacterial contamination is not acceptable for transfusion.	Discoloration due to icterus (yellow), oral contraceptives (green), vitamin A or large quantities of carrots (orange) are all acceptable for transfusion.	Discoloration due to icterus (yellow), oral contraceptives (green), vitamin A or large quantities of carrots (orange) are all acceptable for transfusion.	Discoloration due to icterus (yellow), oral contraceptives (green), vitamin A or large quantities of carrots (orange) are all acceptable for transfusion.

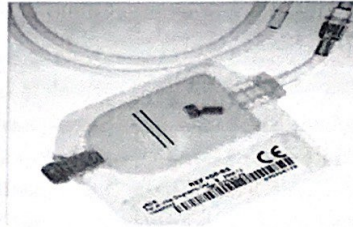
blood components inspection.

5. Screening of platelet components by using the Bacterial Detection System: eBDS

5.1. Description of the system

- The Haemonetics eBDS uses oxygen concentration as a marker for bacterial growth.
- System Components:

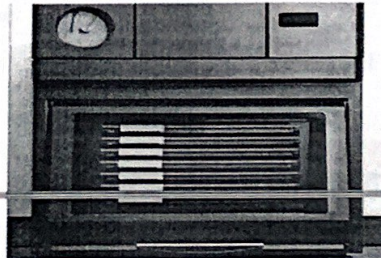
5.1.A. eBDS Sample Set for sample transfer and oxygen sampling.



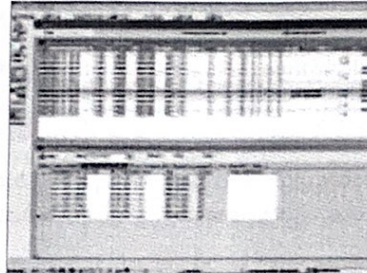
5.1.B. eBDS Oxygen Analyser



5.1.C. Incubation and Agitation: Platelet agitation accelerates bacteria growth and oxygen equilibration between the head space air and fluid.



5.1.D. Haemonetics Data: monitors and manages the entire eBDS process.



5.2. eBDS Process Flow:

- 5.2.1. The Blood bank technician sterile connects the eBDS Sample Set to the platelet product using the Welder system 24 hours or longer after collection and separation.
- 5.2.2. The Blood bank technician bauble clicks on Pall Data Shortcut then log in by entering the username ENGINEER and password ENGINEER then presses WORKFLOW then presses ADD SAMPLE then enters donation ID of the platelet product then TAB then product code plt then TAB then scanning the eBDS pouch using the gray scanner.
- 5.2.3. The Blood bank technician clamps the tubing of the Sample Set below the check valve.
- 5.2.4. The Blood bank technician suspends or holds the blood component pack above the sample pouch ensuring the fill lines are horizontal.
- 5.2.5. The Blood bank technician opens clamp and allow fluid to flow until the fluid level reaches at or between the two lines located on sample pouch.
- 5.2.6. (The pouch is considered "underfilled" if the liquid level is below the first line, and "overfilled" if liquid level is over the second line.) Overfill of the sample pouch can result in a false positive. Underfill can result in a false negative.
- 5.2.7. The Blood bank technician clamps the tubing.
- 5.2.8. The Blood bank technician seals tubing on both sides of the check valve.
- 5.2.9. The Blood bank technician detaches the check valve from sample pouch and blood component pack and discards check valve.
- 5.2.10. The Blood bank technician places the sample pouch on horizontal platelet agitator inside a 35°C incubator for 18-48 hours.
- 5.2.11. The Blood bank technician returns the blood component bag to storage.
- 5.2.12. The Blood bank technician measures the percentage of oxygen in the headspace of the sample pouch within the specified 35°C incubation period
- 5.2.13. The Blood bank technician confirms that the eBDS Oxygen Analyzer is ready to measure sample, if not he presses two times on the Left Arrow.
- 5.2.14. The Blood bank technician handles the pouch and orient sample site in the vertical

position. Insert probe of the oxygen analyzer through the sampling site septum and protective membrane into the headspace air of the sample pouch.

Notes:

- Do not hold/squeeze body of sample pouch when inserting probe, pressure may activate alarm on oxygen analyzer.
- Do not insert probe into liquid in the sample pouch.
- Do not use alcohol to cleanse sampling site. Alcohol may interfere with the oxygen analysis.

5.2.15. The Blood bank technician measures the percentage of oxygen by aspirating the headspace air of the sample pouch.

- If "Pass" is displayed, the test did not detect bacterial contamination and indicates the sample is NEGATIVE at the time of oxygen measurement.

The Blood bank technician documents the result and discards the eBDS sample pouch. A flashing "FAIL" indicates that the percentage of oxygen is less than the acceptable limit.

- If a flashing "FAIL" is indicated, it is likely that the sample is contaminated with bacteria, and it is recommended that the blood component unit is discarded after culturing to confirm result.

The Blood bank technician performs the culture of the positive units to confirm the result and discards the units of platelets, plasma and packed red cells.

6. **Screening of platelet components by using the blood culture:**

6.1. The Blood bank technician performs the culture of all platelet's units produced by:

- Recording platelets units' numbers in platelets culture form
- Label the pediatric culture bottles (pink top)
- Removing the cap and disinfect the septum with an alcohol swab and allow to dry.
- Cut the segment attached to the platelet unit (minimum 10 cm of length).
- Disinfect the segment with an alcohol swab and draw 1 ml to 3 ml of platelets by syringe and empty content in the corresponding culture bottle then mix thoroughly by gentle inversion.
- Give the blood culture bottles to the microbiology department so that they put them in the

incubator for 5 days. We are informed by the microbiology department for Preliminary result after 48 hours.

- 6.2. If the blood culture is negative so the platelets units are not contaminated and the unit will be labeled as: Bacterial contamination not detected at the date of issue.

7. If any positivity occurs, the cause is analyzed:

- First the Blood bank staff (technician, supervisor or doctor) discards the units of platelets till investigations are finished.
- The Blood bank staff quarantines the associated units of Packed red cells and plasma till investigations are finished.
- The Blood bank staff performs the culture from the segments of Packed red cells and plasma and the results are compared with those of platelets culture, if positive the units are discarded.
- The Blood bank supervisor or the Blood bank doctor asks the technician who withdrew the unit and asks him if he cleansed the site of phlebotomy as recommended, then reviews the history of the donor is there any history of bacteremia.
- The Blood bank supervisor or the Blood bank doctor asks the technician who processed the unit in the separation area, is there any history of leaky seals, damaged tubing or micro-punctures in collection bags.
- The Blood bank supervisor or the Blood bank doctor checks the temperature of the platelet incubator.

05. Responsibilities :

- 05.1. All laboratory staff of Alqunfudah General Hospital.

06. Equipment & Forms

- 06.1. Visual guide for blood components inspection. Results of bacterial detection (print outs from eBDS or blood culture results).

07. Attachment :

N/A

08. Reference



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08.1. AABB technical manual.

08.2. Haemonetics eBDS manual guide.

Preparation, Reviewing & Approval Box

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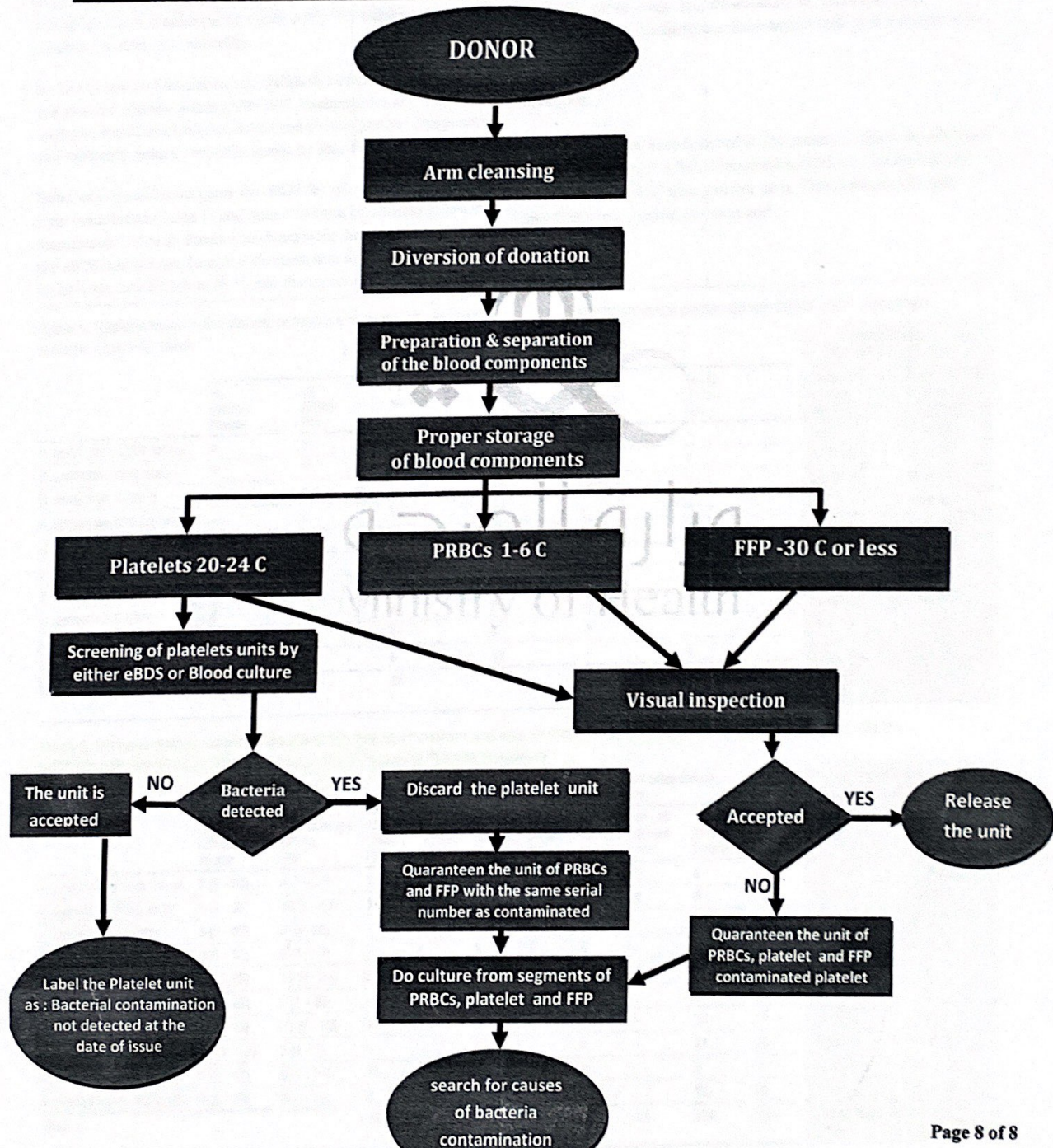
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Al Qunfudah General Hospital

Appendix A: (Process for the reduction & detection of bacterial contamination of blood components) :



Performance Summary for the Haemonetics eBDS™

The ten organisms that were selected for determining the performance characteristics of the Haemonetics eBDS were the same genus and species as those responsible for over 98% of all fatalities associated with the transfusion of bacteria contaminated platelets¹. The exact slow growing organisms isolated from platelet components were used rather than similar fast growing isolates ensuring real world reliability. The organisms were tested in platelet products prepared from whole blood-derived platelet rich plasma, buffy coat and apheresis. A similar performance study was conducted to validate the testing of red cells.

Data is shown and available from validation studies in both plasma and platelet additive solution (PAS)²⁻¹². Haemonetics eBDS is approved for all routinely used PAS and plasma platelet components and leucocyte reduced red cells stored in SAG-M^{13, 14}.

Samples were collected using the eBDS Sample Set immediately after inoculation (Table 1), and after a 24 hour incubation following inoculation (Table 2). Platelet products were inoculated prior to using the eBDS Sample Set. Sample collection into the pouch was followed by 24 hour incubation at 35 °C and thereafter tested.

Sensitive*

- 96.6% (plasma) and 90.7% (PAS) of all samples tested positive when sampling occurred immediately following inoculation.

Table 2 illustrates that:

- 100% of all samples tested positive when sampling occurred after a 24 hour incubation at room temperature.

An independent study⁷ has shown eBDS to be of equivalent sensitivity to an established culture based method in a side-by-side controlled study.

Specific

No false positives were detected in the control samples. Routine use monitoring of the 118,067 Haemonetics eBDS test resulted in only 76 (1/1554 or 0.06%) false positive tests. This confirms the high specificity in a routine environment².

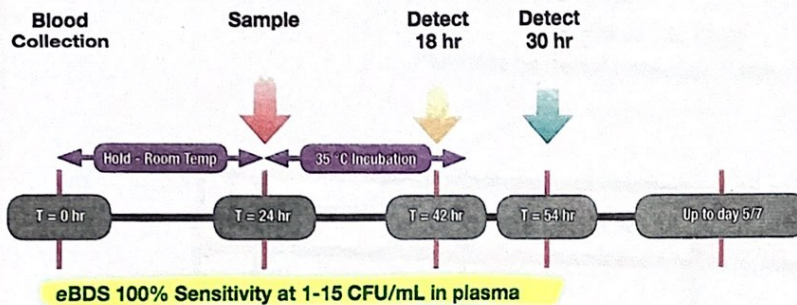
Table 1. Bacteria levels in the platelet products and detection with sampling from the platelet products performed immediately after inoculation (Sample Time = 0 hours).

	Bacteria level immediately after inoculation and sampling (Sample Time = 0 hours)						Detection with Sample Time = 0 hours	
	≤5 CFU/mL Plasma	≤5 CFU/mL PAS	6 - 15 CFU/mL Plasma	6 - 15 CFU/mL PAS	16 - 50 CFU/mL Plasma	16 - 50 CFU/mL PAS	Cases detected of cases sampled Plasma	Cases detected of cases sampled PAS
<i>S. epidermidis</i> (ATCC 49134)	4	17	1	9	-	-	5 of 5	25 of 26
<i>S. agalactiae</i> (ATCC 12927)	5	7	4	18	2	1	11 of 11	25 of 26
<i>S. aureus</i> (ATCC 27217)	-	6	5	17	4	3	9 of 9	26 of 26
<i>P. aeruginosa</i> (ATCC 27853)	-	5	11	17	-	4	8 of 11	12 of 26
<i>S. choleraesuis</i> (ATCC 8326)	4	2	2	18	5	6	11 of 11	26 of 26
<i>E. coli</i> (ATCC 25922)	1	8	6	14	-	2	7 of 7	19 of 20
<i>E. cloacae</i> (ATCC 29005)	-	1	6	14	-	5	6 of 6	20 of 20
<i>B. cereus</i> (ATCC 7064)	2	15	6	2	4	-	12 of 12	16 of 17
<i>K. pneumoniae</i> (ATCC 8045)	3	12	7	8	1	-	11 of 11	17 of 20
<i>S. marcescens</i> (ATCC 43862)	-	9	5	10	-	1	5 of 5	20 of 20
Total	19	82	53	123	16	22	85 of 88 (96.6%)	206 of 227 (90.7%)

Table 2. Bacteria levels in platelet products at the time of inoculation and after 24-hour storage at which time samples were taken into the eBDS Sample Set (Sample Time = 24 hours), and the resulting detection frequency.

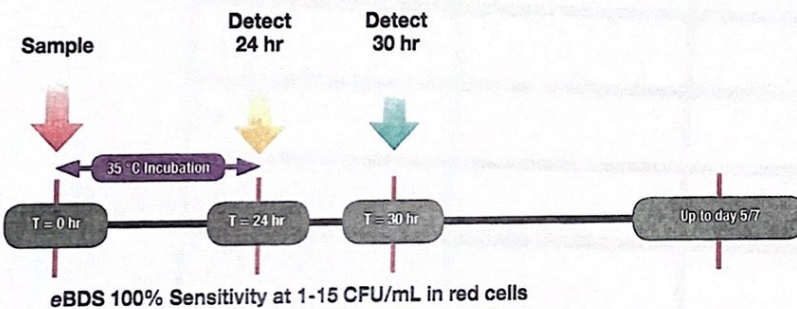
	Inoculation bacterial level		Bacteria level at sampling time after 24 hours storage (Sample Time = 24 hours)								Detection with Sampling at 24 hours	
	Median (range) CFU/mL Plasma	Median (range) CFU/mL PAS	≤5 CFU/mL Plasma	≤5 CFU/mL PAS	6 - 15 CFU/mL Plasma	16 - 50 CFU/mL PAS	16 - 50 CFU/mL Plasma	16 - 50 CFU/mL PAS	≥51 CFU/mL Plasma	≥51 CFU/mL PAS	Cases detected of cases sampled Plasma	Cases detected of cases sampled PAS
<i>S. epidermidis</i> (ATCC 49134)	7 (2 - 52)	4 (1 - 10)	1	15	15	7	8	2	3	2	27 of 27	25 of 25
<i>S. agalactiae</i> (ATCC 12927)	5 (2 - 20)	10 (1 - 17)	3	6	7	2	9	8	9	10	28 of 28	26 of 26
<i>S. aureus</i> (ATCC 27217)	8 (2 - 51)	8 (3 - 25)	-	-	-	2	5	-	24	24	29 of 29	26 of 26
<i>P. aeruginosa</i> (ATCC 27853)	9 (1 - 15)	8 (3 - 17)	-	-	1	1	4	-	19	24	24 of 24	26 of 26
<i>S. choleraesuis</i> (ATCC 8326)	8 (1 - 55)	10 (2 - 34)	6	-	0	3	2	7	16	9	24 of 24	22 of 22
<i>E. coli</i> (ATCC 25922)	6 (2 - 15)	6 (1 - 20)	-	-	-	-	-	-	27	20	27 of 27	20 of 20
<i>E. cloacae</i> (ATCC 29005)	8 (2 - 13)	13 (5 - 32)	4	-	4	1	4	-	16	19	28 of 28	20 of 20
<i>B. cereus</i> (ATCC 7064)	13 (3 - 27)	3 (1 - 7)	-	-	-	-	2	-	31	20	33 of 33	20 of 20
<i>K. pneumoniae</i> (ATCC 8045)	5 (1 - 17)	5 (1 - 14)	12	-	9	-	3	2	9	17	33 of 33	20 of 20
<i>S. marcescens</i> (ATCC 43862)	9 (1 - 16)	9 (1 - 16)	2	-	-	-	-	-	25	20	27 of 27	20 of 20
Total			28	24	36	17	37	19	179	165	280 of 280 (100%)	225 of 225 (100%)

eBDS™ Sampling Schedule Chart for Platelets

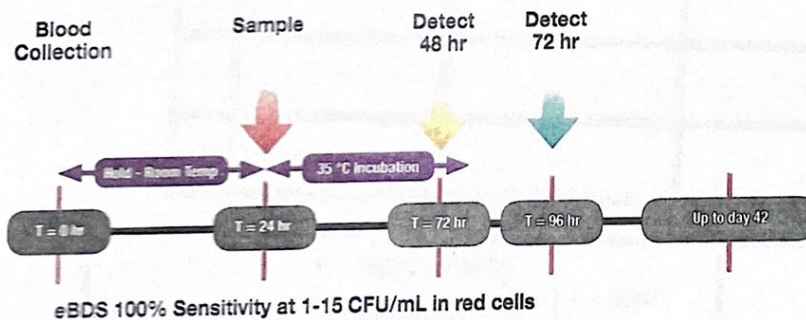


The high sensitivity of eBDS allows for flexible sampling schedules to fit with different blood centre operational logistics:

- Sampling of the platelet unit after 24 hours hold followed by incubation of the eBDS pouch at 35 °C for 18-30 hours.
- Sampling of the platelet unit immediately after collection/preparation followed by incubation of the eBDS pouch at 35 °C for 24-30 hours.
- Red cells may be sampled as soon as 24 hours post donation. The eBDS pouch should be incubated for 48-72 hours.



eBDS Sampling Schedule Chart for Leucocyte Reduced Red Cells in Additive Solution



Kingdom of Saudi Arabia
General Directorate for Health Affairs
Makkah AL-Mukaramah Region
Directorate of Health Affairs Qunfudah Province
AL-Qunfudah General Hospital



المملكة العربية السعودية
المديرية العامة للشئون الصحية بمنطقة مكة المكرمة
مديرية الشئون الصحية بمحافظة القنفذة
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المختبر وبنك الدم

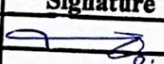


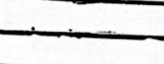
شهادة خلو الصفائح
Platelets bacterial detection Safety Certificate

NO	POOL NO	PLATELET NO.	BACTERIAL DETECTION
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	التوقيع			التوقيع

AL QUNFUDAH GENERAL HOSPITAL

Department: Blood Bank

Signature Sheet For Policy And Procedure				
Policy And Procedure Title		Policy And Procedure No.		
Reduction and detection of Bacterial Contamination of Blood Components		LAB -124		
No.	Name	Title	Signature	Date
1	Mohammed Al Shouni	Lab Tech		12-6-19
2	Ahmad Ali	Lab Tech		12-6-19
3	Ahmed Alqahtani	Lab Tech		12/6/19
4	Hassan Zahra	Lab Tech		12-6-19
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